UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/699,372 | 10/31/2000 | Courtney Hudson | 18966.0002 | 7828 |

23517 7590 02/13/2006

SWIDLER BERLIN LLP
3000 K STREET, NW
BOX IP
WASHINGTON, DC 20007

| EXAMINER | |
|---|---|
| PORTER, RACHEL L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3626 | |

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/699,372 | HUDSON, COURTNEY | |
| | Examiner | Art Unit | |
| | Rachel L. Porter | 3626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-5,7-24 and 39-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-24 and 39-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Notice to Applicant*

1. This communication is in response to the communication filed 11/21/05. Claims 1, 3-5,7-24, and 39-60 are pending. Claims 40-60 are new.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 47-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 48 recites the limitation "the method of claim 47" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 47 and 19 recite a system not a method.

Moreover, it is noted that while exemplary claim 47 recites a "system" in the preamble, it appears to describe a step as part of a process, rather than a system component. Similarly, claim 48 recites a step performed by a user in the system, not a system component. It is therefore unclear how the recited step limitations are intended to further define or distinguish the "system" of claims 19 and 47.

A similar analysis may be applied to claim 53 which simply recites that the user is provided with search engine

Therefore, it is unclear whether the applicant intends to claim a process or a system/apparatus in claims 47-53.

Claims 49-52 inherit the deficiencies of claim 47 and 48 through dependency, and are therefore also rejected.

### *Claim Rejections - 35 USC § 102*

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3-5, 7-14, 17-24,39-43,46-50,53-57, and 60 are rejected under 35 U.S.C. 102(e) as being anticipated by Knight (USPAP 2002/0099570).

[claim 1] Knight discloses a method for matching patients with clinical trials, comprising:

- receiving patient profile information for a patient at a server connected to a computer network, the patient profile information submitted by a user at a terminal connected to the network; (par. 68)
- comparing the patient profile information with acceptance criteria for clinical trials stored in a database, the comparison performed by the server; and (par. 63,69))

- automatically, determining whether the patient prequalified for any of the clinical trials based on the comparison of the patient profile information with the acceptance criteria; and (par. 63)
- if the patient prequalified, for any of the clinical trials notifying the user that the patient has prequalified for at least one specific clinical trial; (par. 73—trial contact information appears)
- presenting to the user a series of questions targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials; (par. 70)
- determining whether the user prequalifies for at least one specific clinical trial based on the users response to the targeted questions; and (par. 70)
- storing the responses to the targeted questions. (par. 70-73)

[claim 3] Knight teaches a method further including providing the user with instructions for enrolling in the clinical trial for which the user has prequalified. (par. 70 and 73)

[claim 4] Knight teaches a method further including asking the user a plurality of questions and creating a patient profile based on the responses to the plurality of questions. (figure 1; par. 68—e.g. gathering demographic data)

[claim 5] Knight teaches a method of claim 4, wherein the step of asking the user a plurality of questions includes: asking the user one or more static questions; asking the

user one or more dynamic questions which are selected based on the user's responses to other static and dynamic questions; and creating a the patient profile based on the responses to the static and dynamic questions. (Figures 1, par. 68, 72-75)

[claim 7] Knight teaches a method of wherein static questions, dynamic questions, and targeted questions are provided with a plurality of answer options, and the user may select one or more answer options in order to answer the questions. (Figure 3-6; par. 75-77)

[claim 8] Knight teaches a method of claim 7, wherein the user is required to submit an answer in a specified format, the specified format being suitable for evaluation by a computer program process. (par. 57: e.g. web-based interface)

[claim 9] Knight teaches a method further including updating the static questions, dynamic questions, or answer options. (par. 84-85)

[claim 10] Knight teaches a method wherein the network is the Internet. (par. 57: e.g. web-based interface; par.75—web pages presented)

[claim 11] Knight teaches a method wherein the user is provided with an application to submit for a clinical trial for which the patient has prequalified. (par. 73—e.g. contact information ; Figures 2, 30)

[claims 12-13] Knight teaches a method wherein the application (i.e. enrollment information) filled out by the user and submitted on-line to the server (Figure 2,), and forwarded to the clinical trial site. (par. 80-81, Figure 30)

[claim 14] Knight teaches a method wherein the patient profile is forwarded to the clinical trial site with the application. (par. 125)

[claim 17] Knight discloses a method wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical trial. (par. 65-68)

[claim 18] Knight teaches a method wherein the acceptance/matching criteria include geographic location. (par. 76/Fig. 4—geographic location and preferences are match criteria)

[claim 19] Knight discloses a system for matching patients with clinical trials, comprising:

- a server connected to a network;(Figure 29)
- a data storage device included in the server, and (Figure 29

- a database located in the data storage device, the database storing patient profile information for a patient and acceptance criteria for a plurality of clinical trials; (Figures 29-30, par. 68)
- the server comparing the patient profile information with the acceptance criteria for the clinical trials stored in the database, (par. 63,69)
- automatically, determining whether the patient prequalifies for any of the clinical trials based on the comparison of the patient profile information with the acceptance criteria; and (par. 63)
- if the patient preaqualifies for any of the clinical trials, notifying the user that the patient has prequalified for at least one specific clinical trial; (par. 73—trial contact information appears)
- presenting to the user a series of questions targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials; (par. 70)
- determining whether the user prequalifies for the at least cone specific clinical trial based on the user's response to the targeted questions: and (par. 70)
- storing the responses to the targeted questions (par. 70-73)

[claim 20] Knight teaches a system wherein the database contains information on disease records; drug records; clinical trial records; and patient profile records. (par. 66; 75-77)

[claim 21] Knight teaches a system wherein a record in the database contains links to other related records. (Fig. 30)

[claim 22] Knight teaches a system wherein the server transmits a plurality of questions to the user over the network, the server also transmits a plurality of answer choices for each question, the server receives responses from the user, and the server builds a patient profile based on the responses. (Figures 1, par. 68, 72-75)

[claim 23] Knight teaches a system wherein the server retrieves a disease/subdisease record corresponding to a disease/sub-disease entered by the user, the disease/-sub-disease record containing links to question records, the server retrieving the question records to access questions to be provided to the user. (Figures 1-2; par. 72)

[Claim 24] The limitations of claim 24 recite a computer executable software instructions for causing a computer to perform the method recited in claim 1. Insofar as the method of claim 1 has been shown to be fully disclosed and computer implemented by the teachings of Knight in the rejection of claim 1, it is submitted that claim 24 is rejected for the same reasons provided in the rejection of claim 1, and incorporated herein.

[claim 39] Knight teaching method comprising the steps of:

- presenting at least one web page to permit an individual to be registered with a database by submitting information indicating whether notice of one or more clinical

studies is desired and registration information, wherein the registration information includes at least a geographic location, a disease condition of interest, and contact Information; (par. 55, par. 128-131)

- automatically registering the individual with the database upon receipt of the registration and indicating information; (par. 131)
- automatically determining, in accordance with the indicating information and the registration information whether to provide notice of a clinical study related to said disease condition; (par. 133)
- providing notice of said clinical study; (par. 133)
- presenting a screening questionnaire associated with said clinical study; and (Figure 10)
- storing in the database answers submitted in response to said questionnaire. (par. 80)

[claim 40] Knight discloses a method further comprising providing a user with an application to submit for the clinical study. (par. 73—e.g. contact information ; Figures 2, 30)

[claims 41-42] Knight teaches a method wherein the application (i.e. enrollment information) filled out by the user and submitted on-line to the server (Figure 2, 30), and forwarded to the clinical trial site. (par. 80-81, Figure 30)

[claim 43] Knight further discloses a method further comprising forwarding the registration (e.g. match data) information to the clinical study site with the application. (Figure 30)

[claim 46] Knight further discloses a wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical study. (par. 65-68)

[claim 47] Knight teaches a server providing a user with an application to submit for the clinical study. (par. 73—e.g. contact information ; Figures 2, 30)
[claims 48-49] Knight discloses that an application is filled out by the user and submitted on-line (Figure 2, 30), and that a server forwards to the application to the clinical study site. (par. 80-81, Figure 30)
[claim 50] Knight discloses that a server forwards the registration (e.g. match data) information to the clinical study site with the application. (Figure 30)

[claim 53] Knight further discloses a system claim 19, wherein the user is provided with a search engine (i.e. that allows the user to search for medical information before selecting a clinical study.) (par. 65-68)

[claim 54] Knight further discloses computer executable software code of claim 24 as explained in the rejection of claim 24. Knight discloses a method further comprising

providing a user with an application to submit for the clinical study. (par. 73—e.g. contact information ; Figures 2, 30).

[claims 55-56] Knight further discloses computer executable software code of claim 24 as explained in the rejection of claim 24. Knight teaches a method wherein the application is (i.e. enrollment information) filled out by the user and submitted on-line to the server (Figure 2, 30), and forwarded to the clinical trial site. (par. 80-81, Figure 30)

[claim 57] Knight further discloses computer executable software code of claim 24 as explained in the rejection of claim 24. Knight further discloses a method further comprising forwarding the registration (e.g. match data) information to the clinical study site with the application. (Figure 30)

[claim 60] Knight further discloses computer executable software code of claim 24 as explained in the rejection of claim 24. Furthermore Knight discloses a method wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical study. (par. 65-68)

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 15-16, 44-45,51-52, and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight in view of Kraftson et al (USPN 6,151,581).

[claim 15] Knight discloses a method wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly disclose that the patient record and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 16] Knight teaches a method further including notifying the clinical trial sponsor when the user submits an application to the clinical trial site. (par. 131)

[claim 44] Knight discloses method a wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly

disclose that the patient registration information and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 45] Knight teaches a method further including notifying the clinical study sponsor when the user submits an application to the clinical study site. (par. 131)

[claim 51] Knight discloses system a wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly disclose that the patient registration information and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight with the teaching of Kraftson to store the patient's information with a patient ID number. As

suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 52] Knight discloses a server notifying the clinical study sponsor when the user submits an application to the clinical study site. (par. 131)

[claim 58] Knight teaches a computer readable medium with executable code as explained in the rejection of claim 24. Furthermore, Knight discloses method a wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly disclose that the patient registration information and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 59] Knight teaches a computer readable medium with executable code as explained in the rejection of claim 24. Furthermore, Knight discloses a method further including a server notifying the clinical study sponsor when the user submits an application to the clinical study site. (par. 131)

***Response to Arguments***

9. Applicant's arguments filed 11/21/05 have been fully considered but they are not persuasive.

(A) On page 13 of the 11/21/05 response, applicant argues that Knight is not valid prior art because there is no inventorship overlap between the provisional application and the Knight application publication, as required by 119(e).

In response, a Correction of Inventorship was filed, naming Stephen C. Knight as an inventor in the in provisional application, 60/227,484. Therefore, the required inventorship overlap does exist between the provisional application and publication and, the Knight reference does qualify as prior art against the applicant's application on this basis.

(B) Applicant argues that elements of claims 11-14 and 17 are not supported by the provisional application. Applicant also traverses the rejections of claims 15-16 (Knight in view Kraftson) for "the same reasons discussed ...with respect to claims 11-14 and 17."

In response, the Applicant has failed to provide a clear statement regarding which aspects of the Knight publication are not supported by Provisional Application 60/938,295. Knight discloses (both in the provisional application and in the application publication) a web-enabled system for allowing users to register and be matched with clinical trials and to submit multi-tiered questionnaires (e.g. generic and trial specific) to the system. (See fig. 2 and 30 PG-pub or Figure 1, 6 in Provisional). Both in the provisional and in publication, Knight discloses a system/method in which patient profile data may be forwarded to clinical trial site (page 19-provisional; par. 130-131 publication) and wherein match information is forwarded to the clinical trial site (Figure 2/1-- pub/ provisional)

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure

- Colon et al (USPN 5,991,731) discloses a web-enabled system that allows patients to answer clinical trial specific questionnaires to determine if they qualify.
- Machlis ("Web Links Cancer Patients to Drug Trials," ) discusses a website used to allow patients and physicians to enter information on drug trials and to find potential trial matches.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RP

ALEXANDER KALINOWSKI
SUPERVISORY PATENT EXAMINER